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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number	:	US 6,890,321 B2
Name of Patentee	:	Luther et al.
Title	:	HARD TIP OVER-THE-NEEDLE INTRAVENOUS CATHETER
Issued	:	May 10, 2005

Group Art Unit: 3742

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

November 2, 2005
(Date)

Vito A. Canuso III, Reg. No. 35,471

REQUEST TO
"MAKE OF RECORD" NOTED ERRORS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Errors by the Patent and Trademark Office have been noted in the recently issued above-identified Letters Patent as follows:

Original Application		Issued Patent		Description of Error
Page	Line	Column	Line	
Page 4 Specification (08-19-2003)	15	3	22 (approx)	Delete "EMBODIMENTS" and insert "EMBODIMENT"
Page 2 Claims (06-07-2004)	Claim 1 Line 2	7	28	In Claim 1, delete "unitaly" and insert "unitary"

Because these are inconsequential errors, a Certificate of Correction is not needed, but it is requested that this Letter be made of record by being included in the patent file.

Please charge any fees to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 11/2/05

By: _____

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material tubing into one end of the soft tubing. When the soft tubing catheter cools, it contracts to tightly surround the hard tubing, making the soft catheter end stiffer than without the inserted segment. An insertion needle with a collar may be used so that the collar engages the proximal end of the hard interior tubing so as to assist in inserting the catheter into the patient's vascular system. In the alternative, an insertion needle with a tapered exterior diameter to tightly engage the interior surface of the hard tubing may also be used to insert the catheter with hard tubing segment.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the invention will now be described with reference to the drawings, which are intended to illustrate and not to limit the invention.

FIG. **1** is a cross-sectional view of the preferred embodiment of the present invention.

FIG. **2** is a cross-sectional view of an alternative embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference may now be made to FIGS. **1** through **2** where the invention may be described in greater detail. With specific reference to FIG. **1**, the present invention is a catheter assembly **10** comprising an over-the needle (OTN) catheter **12** and an insertion needle **14**. The OTN catheter **12** comprises a length of flexible tubing having a lumen therethrough wherein the tubing is made preferably of a soft thermoplastic material such as polyurethane. The polyurethane tubing preferably has a hardness ranging between 50 and 90 on the Shore A scale, more preferably in the range between 65 A and 85 A. The soft resilient material serves to reduce vascular trauma and discomfort when in use as will be understood in the art. A suitable polyurethane is sold under the tradename Carbothanc™ by Thermedics Corporation of Woburn, Mass. It should be recognized that other thermoplastic materials may be used that are soft and resilient and that would be effective at minimizing vascular trauma when being inserted into or residing within a patient's vascular system.

The catheter **12** has a proximal end comprising a hub or fitting **16** and a distal, preferably tapered, end **18**, wherein the distal end is the leading end inserted into the patient along with the insertion needle **14**. The insertion needle **14** has a proximal end comprising a fitting **22**, configured to permit a clinician to safely handle the needle, and a tapered distal end **24** terminating in a sharp point used to pierce a patient's skin and vascular system. The fitting **22** of the insertion needle **14** preferably has a configuration suitable for residing within the fitting **16** on the catheter during catheter insertion. The catheter fitting **16** also preferably comprises a female luer opening with a flange (not shown) for engagement with a fluid supply line having a corresponding Luer or Luer Lock. Such locking elements are well known in the art.

Preferably, the catheter assembly **10** is supplied to a clinician with the insertion needle **14** already inserted through the lumen in the catheter **12**, wherein the exposed tip of the needle and the catheter **12** are enclosed within a protective sheath (not shown). The assembly **10** may, therefore, be easily handled until it is desired to use the assembly. The catheter assembly also preferably includes a guard means for covering the exposed tip of the needle after the needle has been retracted from the patient following catheter insertion. As has been addressed in the prior art, an exposed needle tip creates a problem for the clinician, particularly given the health hazards to clinicians associated with exposure to blood drawn from patients. Numerous means have been developed to automatically ensheathe the tip as the needle is withdrawn from the catheter. An example of such means is the needle tip guard sold by B. Braun Medical Inc. under the trade name Introcan®. Another example is manufactured by Johnson & Johnson and is described in U.S. Pat. No. 4,762,516 to Luther. A method of using the present invention preferably includes the step of providing a guard means that locks into place protecting the needle tip during retraction, as discussed below.

In the preferred embodiment, the distal end **18** of the OTN catheter has been treated via one of several hardening methods, preferably a chemical treatment method, some of which are described further below. As explained above, treating the distal end **18** of the OTN catheter so as to make it stiffer makes it easier to insert the catheter into a patient undergoing treatment. The stiffer end resists rolling up or accordion like scrunching during insertion of the catheter into the patient. Preferably, the polyurethane catheter **12** has been treated with a hard thermoplastic material such that the resulting treated distal end of the catheter **12** has a hardness above 90 on the Shore A scale and, more preferably, a hardness of 99 on the Shore A scale. The extent of treatment is represented by brace **28**, the length of which may be user specified. A soft catheter **12** having at least inches of treatment is effective. However, any length of the distal end of the catheter may be so treated as will be easily understood by those skilled in the art.

The present invention catheter system may also comprise abutment means for further facilitating advancement of a soft material OTN catheter. In one embodiment, the abutment means comprises an abutment shoulder **30** integral with the interior of the catheter **12** and an external collar **32** secured to the insertion needle **14**. The shoulder **30** and the collar **32** are positioned at a distance from the distal end of the catheter and needle, respectively. In one embodiment, when the needle **14** is fully inserted through the catheter **12**, the collar **32** advantageously abuts the interior shoulder **30** to provide leverage in advancing the catheter into the patient during insertion. The collar **32** is preferably positioned on the needle **14** such that it abuts the shoulder when a sufficient portion of the distal end **24** of the needle extends beyond the distal end **18** of the catheter. This leaves the tip of the needle exposed for insertion into the patient. Other embodiments of the abutment means are contemplated by the present invention, such as that described in U.S. Pat. No. 5,531,701 to Luther, which is incorporated in its entirety herein by reference. Moreover, the interior abutment shoulder of the catheter need not be a sharp or angled corner, as illustrated in FIG. **1**, but may be a smooth, less dramatic, transition from a proximal lumen diameter to a smaller distal lumen diameter. Such an arrangement would preferably permit engagement with a complimentary abutment feature on the insertion needle. Other arrangements of abutments may be used so long as they are effective at transferring insertion forces from the needle to the catheter.

Where it is desired to feed the soft material catheter well into the vascular system of the patient and to track the advancement of the catheter during the process, a metal ring **40** may be securely positioned within the lumen **42** of the catheter **12**. Preferably, the metal ring **40** is sized and configured to sit adjacent the interior shoulder **30** within the catheter **12** in a secure position, although a metal ring may be used even where an interior shoulder **30** is not provided. Preferably, the metal ring **40** is press fit into place by, for

catheter cools, it contracts to tightly surround the hard tubing, making the soft catheter end stiffer than without the inserted segment. An insertion needle with a collar may be used so that the collar engages the proximal end of the hard interior tubing so as to assist in inserting the catheter into the patient's vascular system. In the alternative, an insertion needle with a tapered exterior diameter to tightly engage the interior surface of the hard tubing may also be used to insert the catheter with hard tubing segment.

Brief Description of the Drawings

[0011] These and other features and advantages of the invention will now be described with reference to the drawings, which are intended to illustrate and not to limit the invention.

[0012] Figure 1 is a cross-sectional view of the preferred embodiment of the present invention.

[0013] Figure 2 is a cross-sectional view of an alternative embodiment of the present invention.

Detailed Description of the Preferred Embodiment

[0014] Reference may now be made to Figures 1 through 2 where the invention may be described in greater detail. With specific reference to Figure 1, the present invention is a catheter assembly 10 comprising an over-the needle (OTN) catheter 12 and an insertion needle 14. The OTN catheter 12 comprises a length of flexible tubing having a lumen therethrough wherein the tubing is made preferably of a soft thermoplastic material such as polyurethane. The polyurethane tubing preferably has a hardness ranging between 50 and 90 on the Shore A scale, more preferably in the range between 65A and 85A. The soft resilient material serves to reduce vascular trauma and discomfort when in use as will be understood in the art. A suitable polyurethane is sold under the tradename CarbothaneTM by Thermedics Corporation of Woburn, MA. It should be recognized that other thermoplastic materials may be used that are soft and resilient and that would be effective at minimizing vascular trauma when being inserted into or residing within a patient's vascular system.

[0015] The catheter 12 has a proximal end comprising a hub or fitting 16 and a distal, preferably tapered, end 18, wherein the distal end is the leading end inserted into the patient along with the insertion needle 14. The insertion needle 14 has a proximal end

The system further comprises a hard thermoplastic insert **120** within a lumen **122** in the catheter **112**. The insert **120** may be inserted in a manner similar to that described above for the metal ring **40** of FIG. 1. Where a shoulder **130** is provided, the insert **120** may be press fit adjacent the shoulder **130** at or near the distal end **118** of the catheter **112**. The result is that the distal end **118** of the catheter **112** is effectively stiffer than it would be otherwise. The increased resulting stiffness has the advantage of minimizing rolling up and/or accordion-like wrinkling of the soft catheter during insertion. With this alternative arrangement, the needle **14** of FIG. **1** may be used where the collar **32** is sized and configured to abut the proximal end **140** of the hard material insert **120** as it did with the metal ring **40** and the interior shoulder **30** of the embodiment of FIG. **1**. By abutting the proximal end **140** of the hard insert **120**, the needle may facilitate insertion into the patient while avoiding trauma to the patient or vein.

The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiment is to be considered in all respects only as illustrative and not restrictive and the scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. An over-the-needle catheter assembly comprising a catheter of unitaly 1 nstruction made of soft material having a lumen therethrough, said catheter material having a hardness in the range of 50 to 90 on the Shore A durometer scale, said catheter having a distal end integral with said catheter that serves as the leading end when inserted into the patient, said distal end being stiffer than the remaining portion of said catheter so as to facilitate insertion of said catheter into the patient.

2. The catheter assembly of claim **1**, wherein said distal end of said catheter has been treated to a hardness that is above about 90 on the Shore A scale.

3. The catheter assembly of claim **1**, wherein said distal end of said catheter has been chemically treated with a hard thermoplastic material.

4. The catheter assembly of claim **1**, wherein said distal end of said catheter has been treated by radiation.

5. The catheter assembly of claim **1**, further comprising an insert that is configured to be securably positioned within said distal end of said catheter to effectively stiffen said distal end of said catheter.

6. The catheter assembly of claim **1**, further comprising abutment means to enhance insertion of said catheter into the patient.

7. The catheter assembly of claim **6**, wherein said abutment means comprises an interior abutment spaced at a distance from said distal end of said catheter, said abutment defining a transition in the internal diameter of a lumen through said catheter.

8. The catheter assembly of claim **7**, further comprising an insertion needle for inserting said catheter into a patient, wherein said abutment means further comprises an abutment on said insertion needle that is complimentary with said abutment on said catheter.

9. The catheter assembly of claim **8**, wherein said catheter further comprises an interior shoulder and said insertion needle further comprises a collar secured to the exterior thereof, said shoulder and collar configured to abut when said insertion needle is directed through said lumen within said catheter.

10. The catheter assembly of claim **1**, further comprising a metal ring configured to be secured within a lumen of said catheter to permit tracking of said catheter during advancement through the patient's vascular system.

11. The catheter assembly of claim **1**, further comprising a guard that covers the tip of a needle when said needle is withdrawn from said catheter to protect against human contact with the needle tip.

12. A method of using an insertion needle to insert a soft material catheter into a patient comprising the steps of:

providing a catheter assembly including a catheter and an insertion needle where said catheter comprises a unitary length of soft material having a lumen extending therethrough, said catheter material having a hardness in the range of 50 to 90 on the Shore A durometer scale,

treating an integral distal end of said catheter to stiffen the material at said distal end so that it resists the tendency of a patient's skin and vascular system to move said catheter proximally,

introducing an insertion needle through said lumen of said catheter to assist in inserting said catheter,

inserting said catheter assembly into the patient's vascular system, and

withdrawing said needle from said catheter to permit connection of a proximal end of said catheter to a tube for fluid communication therewith.

13. The method of claim **12**, further comprising the step of providing an abutment means for distal engagement between said catheter and said insertion needle, wherein said abutment means permits the transfer of at least some insertion forces from said insertion needle to said catheter to enhance effective advancement of said catheter into the patient.

14. The method of claim **13**, wherein said abutment means comprises an internal abutment in said lumen of said catheter spaced at a distance from said distal end of said catheter, said abutment defining a transition in the diameter of said lumen.

15. The method of claim **14**, wherein said abutment further comprises an abutment on the exterior of said insertion needle configured to abut the abutment of said catheter during the step of inserting the catheter assembly into the patient.

16. The method of claim **12**, further comprising the step of providing a guard that covers a tip of said needle when said needle is withdrawn from said catheter to protect against human contact with said needle tip.

17. The method of claim **12**, wherein the step of treating a distal end of said catheter comprises inserting a hard material insert into said distal end.

18. The method of claim **12**, wherein the step of treating a distal end of said catheter comprises chemically adding a hard thermoplastic material to said catheter to result in a hardness of at least 90 on the Shore A scale.

19. The method of claim **12**, wherein the step of treating a distal end of said catheter comprises chemically treating the distal end of said catheter.

20. A catheter for insertion into the vascular system of a patient, said catheter having a proximal end and a distal end, said catheter comprising a unitary material and of unitary construction, wherein said integral distal end of said catheter is treated such that said distal end of said catheter is harder than said proximal end of said catheter.

* * * * *

AMENDMENTS TO THE CLAIMS

1. **(Original):** An over-the-needle catheter assembly comprising a catheter of unitary construction made of soft material having a lumen therethrough, said catheter material having a hardness in the range of 50 to 90 on the Shore A durometer scale, said catheter having a distal end integral with said catheter that serves as the leading end when inserted into the patient, said distal end being stiffer than the remaining portion of said catheter so as to facilitate insertion of said catheter into the patient.

2. **(Original):** The catheter assembly of Claim 1, wherein said distal end of said catheter has been treated to a hardness that is above about 90 on the Shore A scale.

3. **(Original):** The catheter assembly of Claim 1, wherein said distal end of said catheter has been chemically treated with a hard thermoplastic material.

4. **(Original):** The catheter assembly of Claim 1, wherein said distal end of said catheter has been treated by radiation.

5. **(Original):** The catheter assembly of Claim 1, further comprising an insert that is configured to be securably positioned within said distal end of said catheter to effectively stiffen said distal end of said catheter.

6. **(Original):** The catheter assembly of Claim 1, further comprising abutment means to enhance insertion of said catheter into the patient.

7. **(Original):** The catheter assembly of Claim 6, wherein said abutment means comprises an interior abutment spaced at a distance from said distal end of said catheter, said abutment defining a transition in the internal diameter of a lumen through said catheter.

8. **(Original):** The catheter assembly of Claim 7, further comprising an insertion needle for inserting said catheter into a patient, wherein said abutment means further comprises an abutment on said insertion needle that is complimentary with said abutment on said catheter.

9. **(Original):** The catheter assembly of Claim 8, wherein said catheter further comprises an interior shoulder and said insertion needle further comprises a collar secured to the exterior thereof, said shoulder and collar configured to abut when said insertion needle is directed through said lumen within said catheter.

10. **(Original):** The catheter assembly of Claim 1, further comprising a metal ring configured to be secured within a lumen of said catheter to permit tracking of said catheter during advancement through the patient's vascular system.